K100885



## Summary of safety and effectiveness

JUN - 7 2010

In accordance with section 513 (1) of the SMDA as defined in 21CFR part 807.92
This summary is submitted to obtain Pre market 510(K) notification

1. Submitter, manufacturer

Bistos Co., Ltd.
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Registration number : 3006179052
Tel: 82 2 2108 4626 Fax : 82 2 2108 4629

2. Contact person

Mr. Young Chi / President
Bio-Med USA Inc.
111 Ellison street,
Paterson, NJ 07505. U.S.A.
Tel: 973 278 5222
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E mail: biomedusa@msn.com

3. Name of Device

| | | |
|---|---|---|
| Trade name | : | BT-200T Portable fetal monitor |
| Common or usual name | : | Fetal monitor |
| Regulation number | : | 884.2740 |
| Regulation class | : | II |
| Product code | : | HGM |
| Classification panel | : | Obstetrics / Gynecology |

4. Substantial Equivalence.

Bistos BT-200TFetal monitor is substantially equivalent in Intended use, Design Function, Performing and all used material, direction to use, labeling, software, producing process, Technology/Principle of operation and performance etc to already legally cleared Bistos' BT-200, under 510(K) 052190 on Oct 4, 2005

Comparison with predicate device attached. (A)

5. Device Description

Bistos' BT-200T is a pocket size Fetal Monitor that measures the fetal heart rate and out puts the fetal sound through built-in speaker. By measuring fetal heart rate (FHR), they are able to predict fetal well-being. BT-200T irradiates ultrasound wave to the abdomen of a pregnant women to detect. The Doppler Frequency signal and analyze, displays the heart rate in LCD screen. The device also provides the heart sound from the heart of fetus.

Operating mode

- Pulsed Doppler
- Continuous Doppler
- Uterine Contraction
- Fetal Movement
- Auto on off Switch

Detail, Engineering design. Performing features, Operating mode, attached (B)

6. Device Intended use

BT-200T is pocket size Fetal Monitor for measuring Fetal Heart rate, Pulse Doppler and uterine contraction of pregnant women. It is intended to aid a comprehensive check for the well being of single fetus.

7. Labeling

Back label, Market promoting leaflet designed by labeling requirement regulation under (21CFR part 801) attached (C)

Brochure C-1/2
Back label C-3

8. Biocompatibility test.

All used material of patient contacted part was done Biocompatibility test by NAMSA ( North American Science ) by FDA guidance Blue Book Memo G95-1 use of ISO 10993 Biological Evaluation of Medical Device part 4, 5, 10.

**Body contacting classification:** Surface device, skin, limited less than 24 hrs.

The Skin contacting materials were found to be biocompatible.

Attached the Biocompatibility Certificate. (D)

9. Voluntary performed Clinical safety test result attached (E)

* HR Accuracy Measuring Report (E-1)
* Medical Electrical Equipment test report (E-2)
* CB Test Certificate (E-3)

## Conclusion

Bistos' BT-200T Pocket size Fetal monitor in this submission is substantially equivalent to the already cleared BT-200 under K052190 on Oct 2005 at Design, specification, intended use, used material, direction to use, software, Technology/principal operating and Performing etc in every angles.

The difference between the devices does not raise any new issues of safety or effectiveness

End of Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Bistos Co., Ltd
% Mr. Young Chi
President
BioMed USA, Inc.
111 Ellison Street
PATERSON NJ 07505

JUN - 7 2010

Re: K100885
Trade/Device Name: BT-200T Fetal Monitor
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: March 25, 2010
Received: March 30, 2010

Dear Mr. Chi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

## Indications for use

510(K) Number : K100885

Device Name : Fetal Monitor,

Indication for use : The BT-200T is a Fetal Monitor for measuring Fetal Heart Rate, Data is displayed on a front panel LCD display, Fetal heart may be measured by means of Doppler ultrasound.

Prescription use X and/or Over-the Counter use_____

(Please do not write below this line-continued on another pages if needed

Concurrence of CDRH, office of ~~Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety